REMARKS

Overview

As the examiner has indicated in the referenced Office Action, the original specification of this application disclosed an antibody, L19, whose disclosed sequence contained amino acid sequence errors. These occurred in both the linker portion (where two additional erroneous amino acids were included which did not exist in the actual linker in the actual antibody, L19, as prepared in the examples of this application), and also one amino acid was misidentified in the VL region in comparison to the actual identity of the amino acid at the same position of the actual antibody, L19.

Applicants have not and are not attempting to correct this sequence by making specification changes to reflect the correct sequence which has always existed in the actual antibody, L19, as prepared in the examples of this application. Thus, the procedures, rationale and holding of *Ex parte Maizel* cited by the examiner in paragraph 4 of the Office Action do not apply here.

Rather, as fully discussed in the response of March 10, 2009, applicants are instead employing the procedure sanctioned by MPEP § 2406 and its subparts (particularly 2406.01 and 2406.02), the sequence disclosure-related rules of 37 C.F.R. § 1.800 and its subsequent subparts (particularly § 1.804(b)), and Federal Circuit case law relied on in the mentioned MPEP portions, particularly *Enzo Biochem v. Gen-probe* and *In re Lundak*.

The MPEP and Federal Circuit decisions make clear that enablement and written description of biological materials can be provided by the making a suitable deposit at any time prior to issuance of a patent. Thus, Applicant's ATCC deposit PTA-9529 made on September 30, 2008 provides written description and enablement for the actual L19 antibody which was the subject of the deposit. A copy of the ATCC deposit form is filed herewith.

Also filed is a copy of the previously discussed Neri declaration under 37 C.F.R. § 1.804(b) filed in related case, 10/321,558, which the examiner notes is not of record in the PTO's image file wrapper for this case. An identical declaration for the current case is also filed. This declaration satisfies the requirement of the mentioned rule to establish the identity of the deposited L19 antibody with that prepared in the examples of the above-identified applications. Accordingly, all the requirements of the rules, the MPEP and Federal Circuit case law are satisfied with respect to the sufficiency of the deposit being made in this application, on which

support is based for the claimed diagnostic method based on use of L19 and claimed conjugates of antibody with a molecule capable of inducing blood coagulation and blood vessel occlusion.

Since all the requirements set forth by the rules, the MPEP and Federal Circuit case law have been met, it can be seen that the current claims have an adequate written description based on the deposit and are enabled on at least the same basis. No new matter has been added to the specification because applicants have not tried to replace any of the erroneous sequence information with the correct information, other than by making the deposit in full accordance with the appropriate rules and case law.

Nothing in the rules and case law changes the applicability of the deposit procedure used herein to provide written description and enablement for the subject matter of the claims. This is true of the facts that an erroneous sequence was initially disclosed in this application and that similar erroneous sequences were disclosed for the antibody L19 in other patent applications, literature disclosing the invention and public databases. These simply represent other instances where the same unintended error was made. As the examiner indicates, the errors in the databases correlated with the Pini et al. reference mentioned by the examiner have been corrected. As for the other documents mentioned in the Office Action, the following actions have been taken:

1. Viti et al.

In paragraph 7 of the Office Action, the examiner discusses certain passages of Viti et al. These passages all refer to reference 18 of the Viti et al. publication. Reference 18 is Pini et al. discussed above and in preceding passages of the Office Action. In other words, Viti et al.'s statements with respect to the antibodies E1 and L19 are based upon the work and sequences reported in Pini et al. The examiner is fully aware of this based on the details of paragraph 7 of the Office Action. Since the database changes mentioned above with respect to the deposits mentioned in Pini et al. have now been corrected as recognized by the examiner, it is assumed that these same database changes clarify the fact that Viti et al. simply picked up the same errors made in Pini, et al. This is especially clear in view of the reference in Viti et al. to the very same database deposit explicitly recited in and made in conjunction with Pini et al. See the end of the first paragraph of the "materials and methods" section of Viti et al.

2. U.S. 2004/0001790

Again, the pertinent facts are that the antibody prepared in the examples of the current

application, L19, at the time of its preparation, in actuality had the very same sequence which is that of the ATCC deposit now made by applicants. (Neri declaration). The other sequences attributed to L19 in the '790 application and in the various other documents and databases pointed out by the examiner, were the result of the same unintended error discussed above, all of which have been corrected. Accordingly, it is believed that the various questions and observations in this regard have now been clarified of record. Should the examiner desire any further clarifications, the undersigned requests a phone call so that such clarifications can be expedited. Such action would be very greatly appreciated. (As discussed in the response of September 29, 2009, this particular publication also contains a disclosure which gives the correct length for the L19 linker. In any event, the erroneous parts of the disclosure of '790 application corresponding to the mentioned U.S. publication have now been corrected to be consistent with the true facts.)

The remainder of the office action

The various remaining points made in the Office Action are discussed below in the same order in which they appear in the Office Action.

A new IDS is being filed herewith setting forth the date of reference 94 as identified in the February 8, 2005 IDS. Another copy of the document is also being filed.

The oversight in failing to correct the description of Figure 6 on page 14 of the specification has now been fixed. Appreciation is expressed to the examiner for noting this problem.

A new paper sequence listing and a new electronic version thereof are being filed herewith. These eliminate the reference to SEQ ID NOS: 20 and 21 since these have been cancelled from Figure 6. Appreciation is also expressed to the examiner for pointing out this problem.

As noted above, copies of the Neri declaration and the ATCC deposit form are being filed herewith. As well, an identical declaration referring specifically to the above-identified application is being filed herewith. Note that Examples 2 of this application and of 10/321,558 are identical.

The foregoing discussion of Federal Circuit case law, the MPEP and relevant rules, in conjunction with the ATCC deposit form and statements under 37 C.F.R. § 1.804(b) by Neri are

believed to establish that the alleged problems noted in the Office Action on pages 8-12 are now overcome. That is, all claims have a full written description and do not introduce new matter to the application. The reference to the deposit does not enter new matter into the application. And the sentence added to the specification identifying the deposit and its accession number also do not constitute new matter. All of such additions to the application are expressly sanctioned by the mentioned case law, in particular, *Lundak*, as noted in the mentioned MPEP sections, as well.

Applicants have now corrected the inadvertent oversight of not changing back on page 23 the location of the mutation at position 32. Appreciation is expressed to the examiner for pointing out this problem as well.

The matters raised in paragraphs 10-13 of the Office Action are dealt with above, primarily with the filing of the Neri declaration and the ATCC deposit form. For reasons explained above, there is no new matter introduced into any claim or by any specification amendments, under the rules, the MPEP and controlling Federal Circuit case law.

Although applicants maintain their position with respect to claim 28 as set forth in the reply of September 29, 2009, in order to expedite prosecution, this claim is now canceled.

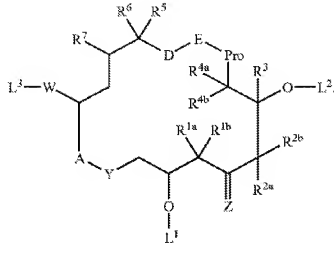
The examiner's rejections under 35 U.S.C. 102(f) and (g) are unsupportable and inappropriate.

The document under which the examiner raises allegations with respect to 102(f) (USP 7,129,254) is effective as a prior art reference only as early as March 5, 2003. This is well after the effective U.S. filing date of the current application which is February 24, 2000 based on parent application 09/512,082. Thus, this document cannot possibly support any sort of prior art allegation. Even if one inappropriately gave relevance to the earliest foreign priority date claimed in U.S. '254 (July 31, 2002), this also is much later than the earliest effective U.S. filing date of the current application.

The examiner further alleges with respect to U.S. '254 that its claims involve a conjugate molecule one of whose portions can be L19. The relevance of this fact is not set forth in the Office Action. L19 is in the prior art with respect to U.S. '254, e.g., in view of its disclosure in Pini et al., discussed by the examiner in the Office Action. Pini et al. was published in 1998 and the earliest claimed U.S. date for U.S. '254 is March 5, 2003, the earliest foreign priority date claimed being July 1, 2002. Thus, there is no inconsistency between L19 being a portion of the

different conjugate molecules recited in U.S. '254 and L19 being a portion of the general conjugates of the current invention. Of course, for the current application, L19 is not in the prior art; rather it is prepared in the examples of the application, as established of record.

Furthermore, all claims of U.S. '254 require that the conjugate has a portion of the Formula I



All conjugates must also have a portion which is "a recognition unit" selected from a wide variety of molecules: peptides, soluble receptors, cytokines, lymphokines, aptamers, spiegelmers, recombinant proteins, new framework structures, monoclonal antibodies and fragments of monoclonal antibodies. As the examiner notes, one of these recognition units can be L19. But this poses no inconsistency or other problem with respect to the current application.

As can be seen, there is nothing in the existence of U.S. '254 which raises any possible problem for the current application, as far as the undersigned understands the examiner's position. Furthermore, this document cannot possibly create any implication of 102(f) prior art for the reasons discussed above. (For the record, the work underlying U.S. '254 was part of a collaboration between the assignee corporation of U.S. '254 and that of the current application.)

Similarly, the rejection under 35 U.S.C. 102(g) is unjustifiable and inappropriate. Firstly, U.S. '254 names only inventors which have residences in Germany. As well, the assignee corporation resides in Germany. Even if the involved dates were somehow relevant, work performed in a foreign country can only be used under 35 U.S.C. 102(g) if "(g)(1) during the

course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof, the invention was made by such other inventor and not abandoned, suppressed or concealed." There has been no such showing in an interference with respect to '254. Consequently, 102(g) is not at all implicated by the existence of U.S. '254.

Furthermore, for all the reasons stated above with respect to the possible dates of U.S. '254 as prior art in the U.S. and possible dates of the work performed with respect to U.S. '254, this document raises no prior art issues of any kind in view of the earliest effective filing date of the above-identified application.

Furthermore, as also noted above, the subject matter claimed in U.S. '254 is not drawn to any invention claimed or disclosed in the current application. The current application contains no disclosure or claim reciting anything like Formula I required in all embodiments of the subject matter claimed in U.S. '254. Consequently, under the "two-way test," applied by the PTO in deciding whether an interference is applicable, for this reason alone, an interference would be inappropriate. The claims of the current application and the claims of U.S. '254 are simply not drawn to the same invention. The examiner's allegation with respect to "a disclaimer of the subject matter" is completely inappropriate and unjustified. Applicants have no obligation or even possibility to present claims or take any steps with respect to an interference with subject matter of U.S. '254 for the reasons discussed above. There is no concession or disclaimer by any action taken or not taken in the current application for any subject matter of either the current application or that of U.S. '254.

The examiner makes a "same-type" double patenting rejection in paragraph 24 of the Office Action. This is made with respect to U.S. 10/321,558. However, the claims of the latter application are not drawn to the same subject matter as the claims of the current application. The mentioned claims 42-49, 59 and 61 of 10/321,558 are drawn to antibodies *per se*. In contrast, none of the claims of the current application are drawn to an antibody *per se*. Thus, it is unambiguous that there is no same-type double patenting between the two applications.

The examiner also alleges in paragraph 25 that the claims of the current application constitute obviousness-type double patenting with respect to the claims of U.S. application 10/336,041 (published as 2004/0001790). This also is an unsupportable allegation. The examiner alleges that the claims of this application are "a species" of the cited application. This is simply

incorrect. The claims of 10/336,041 all require a peptide having two components: 1) an antigen-binding site selected from aa, ab, and ac; and 2) an amino acid sequence ba, bb, or bc, wherein the former antigen binding site is bound to the N-terminus of one of the three latter sequences ba, bb, or bc. To the extent one of the antigen binding sites involves L19, it consequently must have bound to its C terminus one of the three mentioned sequences, ba, bb and bc. There is no such binding feature recited in any of the claims of this application or disclosed therein. Given this fact, it is incorrect to state that the claims of U.S. 10/336,041 encompass any of the claims of the current application. Since the claims of 10/336,041 require, when L19 is involved, that the latter have structural modifications which are not part of the current claims, it can be seen that the mentioned application does not render the claims of the current application obvious.

Furthermore, under MPEP 804(I)(B)1, because the current application has an earlier effective filing date than the cited application, even if there were an obviousness situation possible, the current application should be permitted to issue since no claims of 10/336,041 are currently allowed.

As for paragraph 26 of the Office Action, the undersigned is not aware of any additional applications that claim the subject matter of the instant application. As demonstrated above, none of the applications cited by the examiner claim the subject matter of the instant application.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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